REMARKS

Claims 18 to 20 were rejected under 35 U.S.C. 102 (b) as anticipated by Larson, et al, U.S. Patent 3,940,003.

Independent claim 20 is more limited than independent claim 18. Independent claim 20 is drafted using "consisting of" wording and includes the following additional features not included in claim 18: a piston rod (6) with a piston stopper (5) slidably mounted in the syringe body and a removable cap (4) engageable on the plastic hollow spike to close the syringe body.

The claim 18 claims a syringe having the following elements: (a) plastic syringe body; (b) a plastic hollow spike; (c) the hollow spike is in one piece with the syringe body; (d) the plastic hollow spike *is* conical and tapered; (e) the tip of the plastic hollow spike has a bevel (9a), i.e. a slanted cross-cut, extending over the entire diameter; and (f) the dimensions and form of the spike are selected so that the amount of elastomeric particles cut from the penetrated elastomeric closure are reduced, as well as the danger of injury.

Larson, et al, discloses a safety cap 22 for a medical container 10 of a medical substance 56 and needle structure 34 for puncturing the seal of the safety cap 22 mounted on the safety cap. Most of the disclosure in Larson, et al, relates to the structure of the safety cap and the needle structure, which are the invention of Larson, et al, as shown by the claims. The needle structure and the safety cap are, however, integral parts of the vial 10, not of a syringe.

Larson, et al, does not claim a syringe or disclose improvements for syringes generally. Larson, et al, does disclose a conventional hypodermic syringe of the prior art for drawing the medical substance from the vial 10 (column 1, lines 12 to 20; column 4, lines 24 and following). The use of this syringe together with the container 10 with the novel safety cap of Larson, et al, is shown in connection with Figs. 3 and 4. Although the materials used in this prior art hypodermic syringe are not disclosed in Larson, et al, one skilled in the art would expect the syringe barrel to be of glass and the needle to be metal. There is no disclosure in Larson, et al, which would suggest otherwise.

Larson, et al, also discloses another conventional syringe 64 to be used in connection with his novel safety cap 22 and needle structure 34. However this other syringe 64 with a tapering tubular tip (conical) 62. This syringe is closer to applicants' claimed syringe than the syringe of Figs. 3 and 4, because the tapering tubular tip is slightly conical and is in "one-piece" with the syringe body. However this other conventional syringe 64 is distinguished patentably from the syringe of claim 18 and claim 20 because the tapering tubular tip is not beveled to form an eccentric tip for penetrating a closure; that is the function of the needle structure 34 which is part of the cap structure and which is connected with the tip 62, but which is not in "one-piece" with it.

In other words, either the needle structure 34 is **or** is not part of the syringe shown in Fig. 5 of Larson, et al. If it is not part of the syringe, then the disclosure in relation to Fig. 5 does **not** anticipate either claim 18 or claim 20, because the tip 62 is **n t** beveled or cross-cut in a plane that is slanted relative to

the axis of the syringe body, as claimed in claim 18 or claim 20. If the needle structure with the beveled tip is considered part of the syringe shown in Fig. 5, then it is not in "one-piece" with the syringe body, as required by claim 18 or 20.

The advantageous one-piece feature should not be discounted since it provides a reduced chance of leakage, contamination and/or malfunction.

Thus there is no disclosure regarding syringes in Larson, et al, that would anticipate either claim 18 or claim 20. One must not "read-in" to prior art disclosure information that is not actually included in it. One should not read into Larson, et al, that the needle structure 34 on the safety cap 22 is combined with syringe body 64 and tip 62 to "make" a "new" syringe. Larson, et al, never suggests that the needle structure 34 is removed from the safety cap and attached to tip 62 of the syringe body 64 to form new syringe device.

Furthermore the needle structure 34 is clearly not conical so that, even if it were to impermissibly use the erroneous procedure of the previous paragraph, the resulting "new" syringe device would not anticipate the device claimed in claim 18 or 20, because as shown in Figs. 1, 2 and 3 and the needle structure 34 has a circular cylindrical portion 44 as well as the conically tapering beveled tip 38. The needle structure 34 would not be called "conical" by one skilled in the art; it is a combination of cylindrical portion 34 and a conical portion 38.

It is well established that each and every feature and limitation of a claimed invention must be disclosed in a single prior art reference in order to reject the claimed invention under 35 U.S.C. 102 (b) as anticipated. See M.P.E.P. 2131 and the *In re Bond* court opinion cited therein. In the case of the

instant claims the limitations mentioned above completely distinguish the claimed invention from Larson, et al.

The following syringe features are not disclosed in Larson, et al:

(1) Larson, et al, does not disclose that the syringe body is plastic (only parts of the needle structure 34, which is part of the vial 10, not a syringe, are disclosed as being plastic);

(2) Larson, et al, does not disclose that tip of the syringe body is plastic if tip 62 is considered to be the tip of the prior art syringe;

(3) If in contrast the needle structure 34 is considered erroneously to be the tip of a syringe, it is not in "one piece" with the syringe body 64,62 and is not conical because it contains a cylindrical part 44.

As far as the "cap" 24 and 30 of claim 19 goes, it is not a cap that closes the plastic syringe body. When the tip is engaged with it, the tip penetrates it and is not closed by it.

For the foregoing reasons withdrawal of the rejection of claims 18 to 20 under 35 U.S.C. 102 (b) as anticipated by Larson, et al, is respectfully requested.

It is respectfully submitted that one skilled in the art would only arrive at the invention claimed in claims 18 and 20 (minus the features reducing elastomer particle contamination) from the prior art of record by an impermissible use of hindsight using the applicants' specification as a guide to pick and choose elements of the prior art devices to reconstruct the claimed invention. This kind of hindsight reconstruction is not permitted under 35 U.S.C. 103 (a). For example,

the Federal Circuit Court of Appeals has said:

> "As in all determinations under 35 U.S.C. 103, the decision maker must bring judgment to bear. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selected elements from references to fill the gaps". ***In re Gorman***, 18 U.S.P.Q.2d 1885 (Fed. Cir. 1991).

For the foregoing reasons it is respectfully submitted that the claims 18 to 20 should not be rejected under 35 U.S.C. 103 (a) over any of the prior art references, especially Larson, et al.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance, then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Any costs involved should be charged to the deposit account of the undersigned (No. 19-4675). Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,

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